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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,363	11/14/2001	Philip G. Ashton-Rickardt	ARCD:382US	5741

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Priya D. Subramony
Fulbright & Jaworski L.L.P.
Suite 2400
600 Congress Avenue
Austrin, TX 78701

EXAMINER	
SHUKLA, RAM R	
ART UNIT	PAPER NUMBER
1632	13

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/993,363	ASHTON-RICKARDT ET AL.	
	Examiner	Art Unit	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears n the c ver sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-35, 37-4042-44, 48-50 and 61-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-35, 37-4042-44, 48-50 and 61-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment and response filed 6-19-03 have been received and entered. It is noted that applicants in their response refer to a declaration by Raymond M. Welsh, however no such declaration was present in the response. The appendix referred to in the response has two resumes of Dr. Welsh- one NIH type resume and another more detailed resume and research articles. Accordingly, the declaration by Dr. Welsh could not be considered.

2. Claims 1-25, 36, 41, 45-47 and 51-60 have been cancelled.

3. Claims 26, 30, 34, 35, 37-40 and 42 have been amended.

4. New claims 61-74 have been entered.

5. Regarding newly presented claims it is noted that HIV and P19 were elected as species for prosecution in paper # 9 and therefore these claims will be examined to the extent they encompass these species.

6. Claims 26-35, 37-4042-44, 48-50 and 61-74 are pending and under consideration.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 26-35, 37, 42-44, 48-50, 61-65, 67, 71-73 are rejected under 35 U.S.C. 112, first paragraph, as containing which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the previous office action of 3-19-03.

R spons to Arguments

Applicant's arguments filed 6-19-03 have been fully considered but they are not persuasive. Applicants argue that by replacing the term "granzyme inhibitors" with "serpin or serpin mimetic" they have complied with the 112 first paragraph written description requirements. However, these arguments are not persuasive because the claims broadly encompasses any serpin or serpin mimetic that would enhance or induce immunity to any viral infection and that would inhibit granzyme function or activity by any mechanisms. The sections of the specification referred to by the applicants in their response do not describe representative number of species of the serpin or serpin mimetics that would enhance or induce immunity to any viral infection and that would inhibit granzyme function or activity by any mechanisms. All these sections make general statements and do not disclose any specific characteristics or identifying characteristics of the serpins or serpin mimetics encompassed by the claimed invention.

Therefore, the limited information in the specification is not deemed sufficient to reasonably convey to one skilled in the art that the applicant was in possession of the broad genus of the modulators or agents at the time the application was filed and it is concluded that the specification does not meet the written description requirements for reasons of record set forth in the previous office action of 3-19-03 and as discussed above.

9. Claims 26-35, 37-4042-44, 48-50 and 61-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in the previous office action of 3-19-03.

Response to Arguments

Applicant's arguments filed 6-19-03 have been fully considered but they are not persuasive.

Applicants argue that the specification provides substantial amount of information pertaining to enhancing or inducing immunity to a viral infection, however, all the sections of the specifications referred to by the applicants are general statements and do not provide any specific information as to how immunity to any viral infection, in particular HIV will be enhanced or induced. Applicants argue that method to treat HIV disease is discussed on page 10, lines 6-19. Again, indicated section except for making a statement does not provide any specific disclosure how to enhance or induce immunity in a HIV infected subject. Applicants argue that working examples address treatment of viral diseases, however again the working examples disclose LCMV infection in a transgenic mouse that express SP16. It is noted that a HIV infected subject is not a transgenic mouse. A transgenic mouse cannot be compared to a subject since all the cells of mouse have integrated a candidate gene and therefore all the cells will be producing the candidate gene. On the other hand in a subject a vector has to be administered and the specification does not disclose as to how the level of SP16 or a serpin that is similar to a transgenic mouse can be achieved. Additionally, an infected subject will already have a virus-HIV infecting its cells and the serpin will be provided later on. Again, this is in contrast to the model system described by the applicants in the specification where SP16 is expressed and then LCMV infection is carried out. Even if one has to consider the knockout mouse, it cannot be compared to an virus infected subject because unlike the knockout mouse the subject will have the endogenous gene expressed. Therefore, applicants' arguments that the mouse described in the specification is an art-recognized model are not persuasive. It is further noted that while the declaration from the inventor could not be considered, the arts cited in the response have been looked at. While these arts do compared the LCMV infection with HIV infection, they can not provide support for the model used in the specification which is a transgenic mouse infected with LCMV and

therefore, the transgenic mouse infected with LCMV can not be considered HIV infection animal model.

Regarding the issue of unpredictability applicants argued that the art was published 3 years ago in 2000 and that gene therapy clinical trials were not uncommon. It is noted that the instant application was filed in 2001 therefore Romano et al represents the state of the art at the time of the filing of the instant application. Regarding applicants quotation of the abstract from the article, it is noted that Romano et al discusses that at the time of the invention there was no one vector or protocol that could be used for every gene therapy treatment method and treatment in one specific case did not mean that same method could be applied to any other disease. While patent office has issued patents, these patents were issued for specific conditions with specific vectors and such could not be generally used in treating any condition. Regarding applicants arguments that therapies without use in clinic are of value, it is noted that the issue is not use, rather how to use and specification fails to provide an enabling disclosure for the claimed invention as discussed in the previous office action and as discussed above.

In conclusion, although, specific vectors, promoters, genes, and routes of administration might be or may have been effective for treatment of a specific disease providing a specific therapeutic effect, gene therapy as a broad-based art is clearly unpredictable in terms of achieving levels and duration of expression of a gene of interest which results in a therapeutic effect. Accordingly, as set forth in the previous office action of 3-19-03, it is reiterated that in view of the quantity of experimentation necessary to determine the parameters for achieving treatment of any viral infection and any route of administration as broadly claimed, the lack of direction or guidance provided by the specification as well as the absence of working examples with regard to a therapeutic effect, it would have required undue experimentation of one skilled in the art to use the claimed invention as broadly claimed.

10. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632